

Day: Monday Date: 9/5/2005 Time: 10:35:33

Continuity Information for 10/052323

Parent Data

10052323

is a continuation in part of <u>09563826</u>

Which Claims Priority from Provisional Application 60132216

Which is a continuation in part of <u>09533149</u>

Which is a continuation in part of <u>09402527</u>

is a national stage entry of PCT/US98/16739 International Filing Date: 08/13/1998

Which Claims Priority from Provisional Application 60055520

Which Claims Priority from Provisional Application 60075113

Child Data

10116963 is a continuation in part of 09533149 10346021 is a continuation in part of 10116963 PCT/US03/01599 is a continuation of 10052323

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Examiner Number: 77509 / WOITACH, JOSEPH

IFW IMAGE

Secrecy Order: NO

Status Date: 06/28/2005

Group Art Unit: 1632

Interference Number:

Unmatched Petition: NO

<u>L&R Code</u>: Secrecy Code:1

Lost Case: NO

Class/Subclass: 514/044.000

Application Number Information

Application Number: 10/052323

Assignments

Filing or 371(c) Date: 01/18/2002

Effective Date: 01/18/2002

Application Received: 01/23/2002

Pat. Num./Pub. Num: /20030125278

Issue Date: 00/00/0000

Date of Abandonment: 00/00/0000

Attorney Docket Number: 858610-2003.2

Third Level Review: YES Status: 71 /RESPONSE TO NON-FINAL OFFICE ACTION ENTERED

AND FORWARDED TO EXAMINER

Confirmation Number: 3301 Oral Hearing: NO

Title of Invention: IMMUNIZATION OF ANIMALS BY TOPICAL APPLICATIONS OF A

SALMONELLA-BASED VECTOR

Bar Code PALM Location Location	Date Charge to Le	c Charge to Name Em	ployee Name Location
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OBJECTS AND SUMMARY OF THE INVENTION

[0022] Non-invasive vaccination onto the skin (NIVS) can improve vaccination

schemes because skin is an immunocompetent tissue and this non-invasive

procedure requires no specially trained personnel. Skin-targeted non-invasive

gene delivery can achieve localized transgene expression in the skin and the

elicitation of immune responses (Tang et al., 1997) and the mechanism for these

responses is different than that from topical application of protein-based

vaccines in conjunction with cholera toxin (Glenn et al., 1998). These results

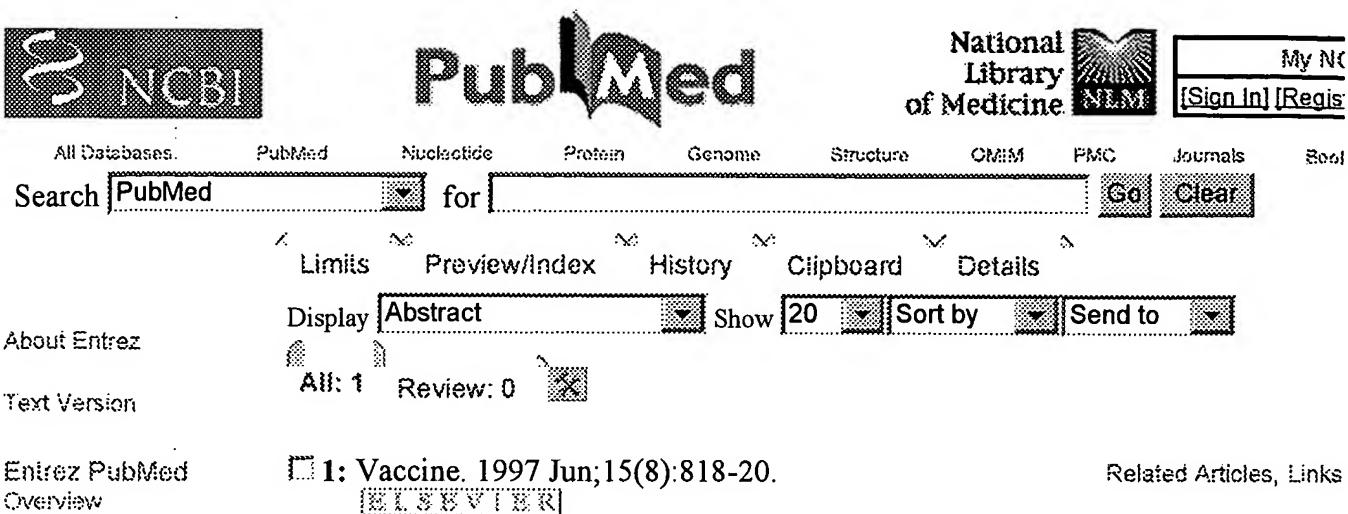
indicate that vector-based NIVS is a novel and efficient method for the

delivery of vaccines. The simple, effective, economical and painless immunization protocol of the present invention should make vaccination less

dependent upon medical resources and, therefore, increase the annual utilization rate of vaccinations.

[0032] Also, the invention provides compositions used in the methods. For instance, the invention provides a prophylactic vaccine or a therapeutic vaccine or an immunological or a therapeutic composition comprising the vector, e.g., for use in inducing or stimulating a response via topical application and/or via mucosal and/or nasal and/or perlingual and/or buccal

and/or oral



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Mucosal immunization with DNA-liposome complexes.

Klavinskis LS, Gao L, Barnfield C, Lehner T, Parker S.

Department of Immunology, Guy's Hospital Medical School, United Medical School of Guy's Hospital, London, UK.

The mucosal surfaces represent the primary site for transmission of several viruses including HIV. To prevent mucosal transmission and dissemination to the regional lymph nodes, an effective HIV vaccine may need to stimulate immune responses at the genital and rectal mucosa. Optimal induction of mucosal immunity in general requires targeting antigens to the specialized antigen presenting cells of mucosal associated lymphoid tissues. The nasal mucosa may provide a simple, non-invasive route to deliver DNA encoding the introduced gene to stimulate mucosal immunity. As a first step to evaluate the feasibility of this approach, we have investigated as a model system, systemic and mucosal immune responses elicited to firefly luciferase generated by DNA immunization. Incorporating DNA into liposomes with cationic lipids enhanced luciferase expression in nasal tissue, and was associated with induction of a humoral response in serum and vaginal fluids and also a proliferative and cytotoxic T lymphocyte response in the spleen and iliac lymph nodes draining the genital and rectal mucosa.

PMID: 9234523 [PubMed - indexed for MEDLINE]

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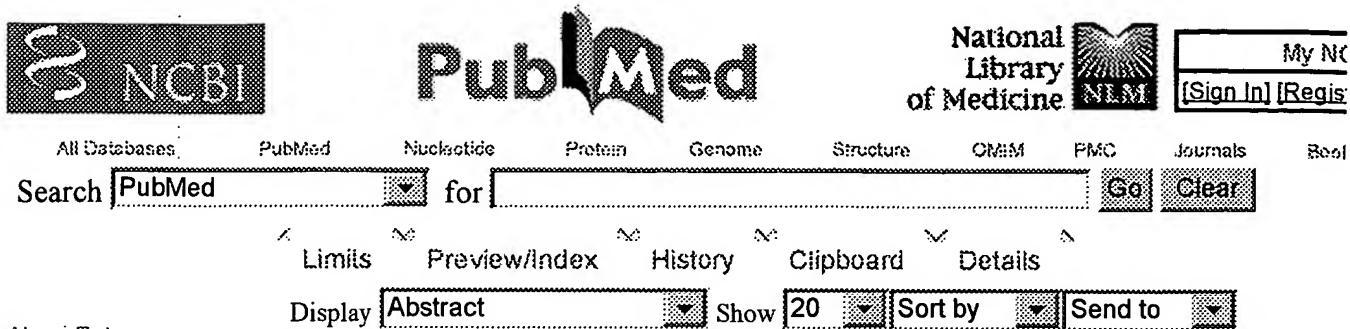
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1: Biochim Biophys Acta. 2002 Aug 15;1572(1):1-9. MISEVIER

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Enhanced delivery of naked DNA to the skin by non-invasive in vivo electroporation.

Zhang L, Nolan E, Kreitschitz S, Rabussav DP.

Department of Research and Development, Genetronics, Inc., San Diego, CA 92121-1334, USA. lzhang@genetronics.com

DNA delivery to skin may be useful for the treatment of skin diseases, DNA vaccinations, and other gene therapy applications requiring local or systemic distribution of a transgene product. However, the effective, consistent and patient-friendly transfection of skin cells remains a challenge. In a mouse model, we evaluated the effectiveness of intradermal injection of plasmid DNA followed by noninvasive in vivo electroporation (EP) as a method to improve transfection in skin. We achieved a several hundred-fold stimulation of gene expression by EP, sufficient to produce clinically relevant amounts of transgene product. We studied the effect of DNA dose and time after treatment as well as various EP pulse parameters on the efficiency of gene expression. EP under conditions of constant charge transfer revealed that the applied voltage was the main determinant for transgene expression efficiency while other pulse parameters had lesser effects. Patient-friendly, noninvasive meander electrodes which we designed for clinical applications proved equally effective and safe as plate electrodes. We also showed for the first time that noninvasive EP is effective in stimulating transfection and gene expression in human skin, particularly in the epidermis. Our findings demonstrate the applicability of EP-enhanced DNA delivery to skin for gene therapy, DNA immunization and other areas.

PMID: 12204326 [PubMed - indexed for MEDLINE]

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